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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,526	01/04/2002	Harold Mermelstein	JWB-2001-1-P	7302

7590

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James W. Badie, Esq.  
Stoll, Miskin, Hoffman & Badie  
The Empire State Building  
350 Fifth Avenue, Suite 6110  
New York, NY 10118

EXAMINER

BENNETT, RACHEL M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/037,526

Applicant(s)

MERMELSTEIN ET AL.

Examiner

Rachel M. Bennett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 7-12, 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 13-18 and 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The examiner acknowledged receipt of the amendment filed 12/1/03.

#### ***Election/Restrictions***

1. This application contains claims 7-12, 19-24 drawn to an invention nonelected with traverse on 4/16/03. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-6, 13-15, 16-18, 25-31 are drawn to elected subject matter.

#### ***Declaration***

2. In reference to the Declaration of Frank Marchese, it refer(s) only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716.

#### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-6, 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US 6242012), and further in view of Gehling et al. (US 2003/0045829 A1), Remington's Pharmaceutical Science and Stuart et al. (US 20030207971):

Applicants claim a therapeutic composition for treatment of vaginal dryness comprising an effective amount of at least two herbal compounds selected from evening primrose and chasteberry, said two herbal compounds used in combination with olive oil, flax seed oil, or unseeded flax oil, jojoba oil, borage oil, distilled water, propylene glycol and an effective amount of thickening agent to make said composition in gel form.

Newmark et al. discloses a herbal composition which can be used to alleviate the symptoms associated with hormonal imbalance in women contains supercritical extracts of ginger, rosemary and evening primrose oil, and either regular or supercritical extracts of black cohosh, gong quai, achizandra berry, chaste tree berry and rosemary. The herbal composition can be administered topically. In addition to promoting hormonal balance, the herbal composition also sustains warmth and normal fluids for healthy sexual functioning. See abstract. Newmark discloses an herbal composition which is capable of relieving symptoms associated with pre- and postmenopausal hormonal imbalance. The formulation combines the following features: lipxygenase inhibiting constituent compounds (ginger, rosemary); empirically reversed normalizers of hormonal functioning (black cohosh, vitex (chasteberry)); essential fatty acid modulators (evening primrose oil, olive oil) and systemic mood/energy support. See col. 1, lines 12-59. The herbal composition can be applied topically, specifically, ophthalmically, vaginally, rectally, intranasally, and the like. When applied topically, the composition is

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particularly effective in relieving vaginal dryness and improving skin tone. See col. 6, lines 37-48. Formulation for topical administration may include but not limited to lotions, ointments, gels, creams, suppositories, drops, liquids, sprays or powders. Conventional pharmaceutical carriers; aqueous, powder, or oily bases; thickeners may be necessary or desirable. See col. 7, lines 40-47. While Newark teaches both evening primrose and chasteberry in a topical composition, specifically a gel, Newmark does not disclose the composition to include an antibacterial agent. Furthermore, Newmark does not disclose the composition to include propylene glycol, jojoba oil and borage oil.

Gehling et al. disclose a tampon is adapted to deliver a therapeutic agent. See abstract. Alternatively, or in addition, therapeutic and other beneficial agents such as antibacterial agents may be similarly delivered. See page 5, [0052]. Known antibacterial agents in the art are methyl paraben and propyl paraben. Examples of beneficial botanicals may include Agnus castus (Chasteberry) and evening primrose. These botanicals can be combined with other beneficial agents. These beneficial therapeutic agents promote epithelial health in the vaginal region by delivering botanical ingredients with a feminine care device. The idea is to modulate the vaginal environment to enhance the wellness of this anatomical region. These benefits can be rather simple, for example increasing comfort by providing moisturization and/or lubricity. See page 6, [0056]-[0058]. Preparations may include gel, botanical oil in an anhydrous base or polyethylene glycol based system. See page 6, [0059]. Combining the active ingredients with a hydrophobic material such as a solidifying agent; wax, vegetable oil, natural soft material (i.e. cocoa butter), allows gradual diffusion of the active ingredient from the hydrophobic material to the body of the wearer. See page 7, [0068].

Remington's Pharmaceutical Sciences discloses propylene glycol as a humectant, which is a substance that promotes retention of moisture.

Stuart et al. discloses an emollient gel useful as an ingredient in cosmetics. The emollient gel is composed of 40-90% of an oil or blend of oils and 2-6% of a thickening wax, or blend of thickening wax. See abstract. Oils disclosed include jojoba oil and borage oil. See claims.

Absent unexpected results, it is the position of the examiner it would have been obvious at the time the invention was made to have modified the composition of Newmark to add antibacterial agents as taught by Gehling, propylene glycol as taught by Remington's, and jojoba oil and borage oil as taught by Stuart because of the expectation of fighting bacterial infections with the antibacterial agent as taught by Gehling and promoting retention of moisture as taught by Remington's and improving dry skin conditions as taught by Stuart.

6. Claims 16-18, 25-27, 28-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newmark et al. (US 6242012), and further in view of Gehling et al. (US 2003/0045829 A1) and Remington's Pharmaceutical Science.

Applicants claim a therapeutic composition in suppository form, for treatment of vaginal dryness comprising an effective amount of at least two herbal compounds selected from evening primrose and chasteberry, said two herbal compounds used in combination with olive oil, propylene glycol and a wax, specifically cocoa butter.

Newmark et al. discloses a herbal composition which can be used to alleviate the symptoms associated with hormonal imbalance in women contains supercritical extracts of ginger, rosemary and evening primrose oil, and either regular or supercritical extracts of black cohosh, gong quai, achizandra berry, chaste tree berry and rosemary. The herbal composition

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can be administered topically. In addition to promoting hormonal balance, the herbal composition also sustains warmth and normal fluids for healthy sexual functioning. See abstract. Newmark discloses an herbal composition which is capable of relieving symptoms associated with pre- and postmenopausal hormonal imbalance. The formulation combines the following features: lipxygenase inhibiting constituent compounds (ginger, rosemary); empirically reversed normalizers of hormonal functioning (black cohosh, vitex (chasteberry)); essential fatty acid modulators (evening primrose oil, olive oil) and systemic mood/energy support. See col. 1, lines 12-59. The herbal composition can be applied topically, specifically, ophtamically, vaginally, rectally, intranasally, and the like. When applied topically, the composition is particularly effective in relieving vaginal dryness and improving skin tone. See col. 6, lines 37-48. Formulation for topical administration may include but not limited to lotions, ointments, gels, creams, suppositories, drops, liquids, sprays or powders. Conventional pharmaceutical carriers; aqueous, powder, or oily bases; thickeners may be necessary or desirable. See col. 7, lines 40-47. While Newark teaches both evening primrose and chasteberry in a topical composition, specifically a suppository, Newmark does not disclose the composition to include an antibacterial agent. Furthermore, Newmark does not disclose the composition to include propylene glycol or wax.

Gehling et al. disclose a tampon is adapted to deliver a therapeutic agent. See abstract. Alternatively, or in addition, therapeutic and other beneficial agents such as antibacterial agents may be similarly delivered. See page 5, [0052]. Known antibacterial agents in the art are methyl paraben and propyl paraben. Examples of beneficial botanicals may include Agnus castus (Chasteberry) and evening primrose. These botanicals can be combined with other beneficial

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agents. These beneficial therapeutic agents promote epithelial health in the vaginal region by delivering botanical ingredients with a feminine care device. The idea is to modulate the vaginal environment to enhance the wellness of this anatomical region. These benefits can be rather simple, for example increasing comfort by providing moisturization and/or lubricity. See page 6, [0056]-[0058]. Preparations may include gel, botanical oil in an anhydrous base or polyethylene glycol based system. See page 6, [0059]. Combining the active ingredients with a hydrophobic material such as a solidifying agent; wax, vegetable oil, natural soft material (i.e. cocoa butter), allows gradual diffusion of the active ingredient from the hydrophobic material to the body of the wearer. See page 7, [0068].

Remington's Pharmaceutical Sciences discloses propylene glycol as a humectant, which is a substance that promotes retention of moisture.

Stuart et al. discloses an emollient gel useful as an ingredient in cosmetics. The emollient gel is composed of 40-90% of an oil or blend of oils and 2-6% of a thickening wax, or blend of thickening wax. See abstract. Oils disclosed include jojoba oil and borage oil. See claims.

Absent unexpected results, it is the position of the examiner it would have been obvious at the time the invention was made to have modified the composition of Newmark to add antibacterial agents and wax, such as cocoa butter as taught by Gehling and propylene glycol as taught by Remington's and jojoba oil and borage oil as taught by Stuart because of the expectation of fighting bacterial infections with the antibacterial agent as taught by Gehling and promoting retention of moisture as taught by Remington's and improving dry skin conditions as taught by Stuart. Furthermore, it would have obvious to add a wax, such as cocoa butter as



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taught by Gehling, to Newmark since both Gehling and Newmark teach a suppository composition and coca butter is taught by Gehling to be used in suppository compositions.

***Response to Arguments***

7. Applicant's arguments with respect to claims 1-6, 13-15, 16-18, 25-31 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (571) 272-0589. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmb

*James M. Spear*  
JAMES M. SPEAR  
PRIMARY EXAMINER  
Au 1615